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| 09/941,769      | 08/30/2001  | Atsumu Hirabayashi   | 1021.40593X00       | 7364             |

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EXAMINER

CHAKRABARTI, ARUN K

| ART UNIT | PAPER NUMBER |
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1634

DATE MAILED: 10/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/941,769

Applicant(s)

Hirabayashi

Examiner

Arun Chakrabarti

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1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/30/01, 10/01/01, 11/28/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/941,769.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other:

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**,DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rejected over the recitation of the phrase, "system administrator". It is not clear what system is claimed in this invention. Is the biological system claimed or chemical system claimed or biochemical system claimed or computer software system is claimed or all of them claimed. The metes and bounds of the claim is vague and indefinite.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-6 are rejected under 35 U.S.C. 102 (b) as being anticipated by Koster (U.S. Patent 5,605,798) (February 25, 1997).

Koster teaches a DNA analysis system for analysis system for analyzing DNA polymorphism (Abstract), comprising:

a) ionization means for generating plural kinds of multiply-charged ions of a test DNA fragment, where each of them has five or more charges (Example 2, Figures 11B and C, Column 2, lines 46-61, and Column 11, lines 2-10);

b) mass spectrometric means for performing a mass spectrometry on the multiply-charged ion formed by the ionization means (Example 2, Figures 11B and C, and Column 11, line 2 to Column 12, line 23);

c) analyzing-result prediction means that predicts a mass spectrum pattern from the mass spectrometric means in each of two cases, where one is that the test DNA fragment is polymorphic and the other is that the test DNA fragment is not polymorphic, based on both information about the test DNA fragment and information about a polymorphism point (Figure 1C);

d) comparative processing means for comparing a plurality of the mass spectrum patterns predicted by the analyzing-result prediction means with the analyzing results of the test DNA fragment analyzed by the mass spectrometric means to determine a nucleic acid base on the polymorphism point (Figure 1c, 2-3, and Figure 11, and Column 11, line 10 to column 12, line 23).

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Koster teaches a DNA analysis system, wherein the analyzing-result prediction means predicts a mass-to-charge ratio ( $m/z$ ;  $m$  is an ion mass,  $z$  is the number of electric charges) of the plural kinds of multi-charged ions and a distribution of ion intensities in each of two cases, where one is that the test DNA fragment is polymorphic and the other is that the test DNA fragment is not polymorphic (Figure 1C).

Koster inherently teaches a DNA analysis system, further comprising:

a) sampling means for supplying a sample including test DNA fragments to the ionization means at fixed intervals (Example 2); (the inference is deduced from the fact that any electrospray mass spectrometer, as taught by Koster, essentially contains a sampling means for supplying a sample at fixed intervals);

b) detecting-output analysis means for subtracting a mass spectrum obtained as an analyzing result with respect to a sample previously measured and modified by weight from a mass spectrum obtained as a detecting-output of the mass spectrometric means (Example 2, and Figure 11), wherein

the mass spectrum processed by the detecting-output analysis means is provided as an analyzing result with respect to the test DNA fragment in the sample (Figure 1C).

Koster teaches a DNA analysis system, wherein the ionization means generates multiply-charged ions of the test DNA fragment by the ionization means using an air atomization (Example 2 and Column 2, line 45 to Column 3, line 14).

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Koster teaches a DNA analysis system, wherein a nucleic acid base of a single nucleotide polymorphism point in the test DNA fragment is specified (Column 10, line 46 to Column 12, line 30).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-10 are rejected under 35 U.S.C. 103 (a) over Koster (U.S. Patent 5,605,798) (February 25, 1997) in view of Haff et al (U.S. Patent 5,885,775) (March 23, 1999).

Koster teaches the DNA analysis system of claims 1-6 as described above including the plurality of measurement systems, where each of the measurement systems comprises the

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sampling means, the ionization means, and the mass spectrometric means (Figures 6B and 6C, and Column 9, lines 27-42) as well as on-line data transfer to a computer (Column 2, lines 33-40).

Koster does not teach the DNA analysis system comprising display means for displaying the occurrence of an emergency when a maximum ion intensity detected by the mass spectrometric means is smaller than a predetermined threshold and communication means for sending information about the occurrence of the emergency to a system administrator.

Haff et al teach the display means for displaying the occurrence of an emergency when a maximum ion intensity detected by the mass spectrometric means is smaller than a predetermined threshold and communication means for sending information about the occurrence of the emergency to a system administrator (Column 6, lines 40-60 and Figure 14).

Koster does not teach the DNA analysis system when a maximum ion intensity of a mass spectrum of the standard sample detected by the mass spectrometric means is equal to or higher than the threshold, the sample where the maximum ion intensity of the mass spectrum is detected as one smaller than the threshold is re-supplied to the ionization means by the sampling means.

Haff et al teach the DNA analysis system when a maximum ion intensity of a mass spectrum of the standard sample detected by the mass spectrometric means is equal to or higher than the threshold, the sample where the maximum ion intensity of the mass spectrum is detected as one smaller than the threshold is re-supplied to the ionization means by the sampling means (Column 6, lines 40-60 and Figure 14).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the display means for displaying the occurrence of an emergency when a maximum ion intensity detected by the mass spectrometric means is smaller than a predetermined threshold and communication means for sending information about the occurrence of the emergency to a system administrator of Haff et al. in the method of Koster, since Haff et al state, "The present invention relates to a method for quickly determining polynucleotide sequences, with low labor intensity and low cost per SNP assay (Column 1, lines 44-46)." By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the display means for displaying the occurrence of an emergency when a maximum ion intensity detected by the mass spectrometric means is smaller than a predetermined threshold and communication means for sending information about the occurrence of the emergency to a system administrator of Haff et al. in the method of Koster in order to improve the process for determining polynucleotide sequences and also in order to achieve the express advantages, as noted by Holtzman, of an invention which relates to a method for quickly determining polynucleotide sequences, with low labor intensity and low cost per SNP assay.

7. Claims 1-12 are rejected under 35 U.S.C. 103 (a) over Koster (U.S. Patent 5,605,798) (February 25, 1997) in view of Haff et al (U.S. Patent 5,885,775) (March 23, 1999) further in view of Harris et al. (U.S. Patent 4,353,242) (October 12, 1982).



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Koster in view of Haff et al teach the DNA analysis system of claims 1-10 as described above.

Koster in view of Haff et al do not teach the system wherein the occurrence of the emergency information is transmitted to sampling means of another measurement systems.

Harris et al. teach the analysis system, wherein the occurrence of the emergency information is transmitted to sampling means of another measurement systems (Column 8, lines 8-19).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the analysis system, wherein the occurrence of the emergency information is transmitted to sampling means of another measurement system of Harris et al in the method of Koster in view of Haff et al, since Harris et al state, "A computer is typically used as a backup with all such combined systems to tie everything together (Column 8, lines 15-17)." By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the analysis system, wherein the occurrence of the emergency information is transmitted to sampling means of another measurement system (e.g., another computer) of Harris et al in the method of Koster in view of Haff et al in order to improve the process for determining polynucleotide sequences and also in order to achieve the express advantages, as noted by Harris et al, of an invention which provides a computer that is typically used as a backup with all such combined systems to tie everything together.

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*Conclusion*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

October 7, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600